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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/051,246 06/05/98 DIETLIN

F GEI061

EXAMINER

HM12/0413

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600 THIRD AVENUE
NEW YORK NY 10016

KUMAR, S
ART UNIT PAPER NUMBER

1621
DATE MAILED:

9
04/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/051,246

Applicant(s)
Dietlin et al

Examiner
Shailendra Kumar

Group Art Unit
1621



☒ Responsive to communication(s) filed on Jun 5, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-27 are pending in this application.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by admitted disclosure or XP'739.

Admitted disclosure on page 1, lines 18-20 and XP' 739, in the abstract anticipates instant claims in terms of aqueous composition and water and alcohol composition of paracetamol.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of admitted disclosure, XP 002045739, XP 002045737, XP 002045740, XP 002030816, XP 002030817, Fuisz(US 4,855,326), Ratnaraj et al(US 5,658,919), WO 9523595, and Pitha(US 4,727,064).

Admitted disclosure, on page 1, line 18-21 expressly teach the aqueous solution of paracetamol. XP'739 and XP '817 teach paracetamol composition containing aqueous solution,

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of water and alcohol. XP '737 and XP '740 teach the adjustment of pH in the aqueous solution of paracetamol. XP'816 expressly suggest addition of antioxidant for the stabilization of the paracetamol solution. Fuisz in column 3, lines 60-63 expressly teach aqueous suspension of paracetamol in isopropanol. Ratnaraj et al is teaching composition containing sugar molecule, and sorbitol, see abstract and col 9. WO' 595, teach the composition in about 1% to about 50% of aqueous solution. Pith is cited to show that paracetamol can be combined with various different compositions.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the admitted disclosure by including the pH adjustment, free radical scavenger addition, alcohol addition or in combination with other pharmaceutical composition, as taught by the rest of the references, because those references expressly teach the stable paracetamol composition by addition of various ingredients, as claimed herein, with the reasonable expectation of achieving a successful stable composition, absent evidence to the contrary.

No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shailendra Kumar** whose telephone number is (703) 308-4519. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S.Kumar

4/9/99

A handwritten signature in black ink, appearing to read 'Shailendra Kumar', with a large circular flourish at the end.

Shailendra Kumar
Primary Examiner
Group 1621